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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,360	12/20/2001	Robert John Kodrzycki	FSL 96-1 CIP	4331
36876	7590	12/08/2003	EXAMINER	
MEADWESTVACO CORPORATION 5255 VIRGINIA AVENUE P.O. BOX 118005 CHARLESTON, SC 29423-8005			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	6

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,360

Applicant(s)

KODRZYCKI ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 20, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed December 20, 2001 and August 30, 2001, are attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to transgenic *Pinus* conifer plants transformed by microparticle bombardment with a genetic construct comprising at least one unspecified gene of interest.

The specification describes transgenic *Pinus* conifer plants (*Pinus rigida* x *Pinus taeda* and *Pinus taeda*) transformed by microparticle bombardment with a genetic construct comprising either an *Escherichia coli uidA* visual marker gene or a Tn5 *nptII* selectable marker gene (Examples 1-4, pages 22-41; Figure 1). The specification does not describe the structure or

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function of other genes of interests, or the structure and function of transgenic *Pinus* conifer plants transformed with other genes of interest.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that “A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case Applicant has not described a representative number of species of the genus “gene of interest” that would be used to transform a pine plant. The rejected claims recite no function performed by such a gene of interest, nor any specific structural features unique to members of the genus. The prior art teaches that different genes have different structures and functions, and as a consequence have different effects when expressed in plants transformed therewith. For example, Walter et al. teach that a variety of structurally and functionally distinct genes are being evaluated for use in transforming pine plants, such as *pat* and *csf-r* genes that confer resistance to herbicides, *cad*, *c-omt* and F5H genes that encode enzymes involved in lignin biosynthesis, MADS box genes that encode proteins that regulate reproduction, and a defensin-like gene that encodes a protein that confers resistance to fungal pathogens (Biotechnology in Agriculture and Forestry, 2000, Vol. 44 (Transgenic Trees), pages 193-211, see pages 206-208). Because the genus “gene of interest” that one would use to transform a pine plant is not adequately described, transgenic *Pinus* conifer plants transformed with a genetic construct comprising at least one unspecified gene of interest are also not described.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to transgenic *Pinus* conifer plants transformed by microparticle bombardment with a genetic construct comprising at least one unspecified gene of interest.

The specification discloses how to make transgenic *Pinus* conifer plants (*Pinus rigida* x *Pinus taeda* and *Pinus taeda*) by microparticle bombardment with a genetic construct comprising either an *Escherichia coli uidA* visual marker gene or a Tn5 *nptII* selectable marker gene (Examples 1-4, pages 22-41; Figure 1).

The claimed invention is not enabled because although the specification teaches how to use the disclosed methods to make transgenic pine plants, Applicant has not provided guidance for how to use transgenic pine plants transformed with an *Escherichia coli uidA* visual marker gene or a Tn5 *nptII* selectable marker gene, or how to make and use transgenic pine plants transformed with other genes of interest.

Guidance for using transgenic pine plants is necessary because the effect an expressed gene of interest has on a plant transformed therewith is unpredictable. The effect is unpredictable because the effect is influence by multiple variables which include but are not limited to whether or not the gene is heterologous to the plant to be transformed, the amount, location and timing of gene expression required to achieve a desired effect, the type of promoter and terminator used in the genetic construct, the type of tissue in which the gene is expressed, the stability of the RNA

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transcript transcribed from the gene, the translation efficiency of the RNA transcript transcribed from the gene, and the stability of the recombinant protein encoded by the gene. See for example Kano-Murakami et al. who teach that a rice homeotic *OSH1* gene expressed under the control of three different promoters produces different phenotypic effects in transgenic tobacco plants as a consequence of differences in the level, site and timing of *OSH1* expression (FEBS Lett. 1993 Nov 22;334(3):365-8). Different phenotypic effects would likewise be expected in transgenic pine plants transformed with different genes of interest, or with the same gene of interest expressed under the control of different regulatory sequences. Applicant has not provided guidance with respect to which genes of interest to express in transgenic pine plants, or how to express them, in order to produce pine plants having a particular useful phenotype. Absent such guidance it would require undue experimentation for one skilled in the art to make and use transgenic pine plants transformed with at least one unspecified gene of interest.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to transgenic *Pinus* conifer plants transformed by microparticle bombardment with a genetic construct comprising at least one unspecified gene of interest.

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The specification discloses how to make transgenic *Pinus* conifer plants (*Pinus rigida* x *Pinus taeda* and *Pinus taeda*) by microparticle bombardment with a genetic construct comprising either an *Escherichia coli uidA* visual marker gene or a Tn5 *nptII* selectable marker gene (Examples 1-4, pages 22-41; Figure 1). The specification also asserts that foreign gene transfer methods can be used to confer useful genetic traits, such as herbicide resistance or insect resistance, to transformed plants (page 1). The specification does not, however, disclose a transgenic *Pinus* conifer plant that has either a specific and substantial asserted utility or a well established utility. The claimed transgenic *Pinus* conifer plants do not have a specific and substantial asserted utility or a well established utility because they are not transformed with a specific type of gene whose expression would confer upon the plant a particular phenotypic trait having a real world application, such as drought tolerance, disease resistance, increased growth rate etc. Because the claimed transgenic *Pinus* conifer plants do not exhibit any particular useful phenotypic trait as a consequence of being transformed with some type of specific gene, the invention is not supported by a specific and substantial asserted utility or a well established utility.

Claims 1-21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Walter et al. (WO 97/01641, International Publication Date 16 January 1997, Applicant's IDS).

The claims are drawn to transgenic *Pinus* conifer plants, including *Pinus taeda* and *Pinus radiata* plants and *Pinus* embryogenic tissue and somatic embryos, transformed by microparticle bombardment with a genetic construct comprising at least one unspecified gene of interest.

Walter et al. teach transgenic *Pinus taeda* and *Pinus radiata* plants, including embryogenic tissue and somatic embryos, transformed by microparticle bombardment with a genetic construct comprising either a β -glucuronidase gene of interest or an nptII gene of interest (page 8 line 16 - page 13 line 6; page 25 line 20 - page 26 line 13; Figures 1 and 2).

The transgenic *Pinus* conifer plants taught by Walter et al. differ from the claimed plants only in their method of manufacture. However, the methods used to make the claimed transgenic *Pinus* conifer plants does not appear to confer a unique characteristic to the claimed plants which would distinguish them from the prior art plants, as there are insufficient identifying characteristics set forth in the claims to distinguish the claimed transgenic *Pinus* conifer plants from the transgenic *Pinus* conifer plants of the prior art. See *In re Thorpe*, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process

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of making the product fails to distinguish the products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562, F.2d 1252, 195 USPQ 430 (CCPA 1977).

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC



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